

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)
_____)

MDL No. 2419
Dkt. No 1:13-md-2419 (FDS)

THIS DOCUMENT RELATES TO:)
_____)

Suits Identified in Exhibit A to this)
Memorandum)
_____)

Memorandum in Support of
Motion to Dismiss Plaintiffs' Complaints
Against Tennessee Health Care Providers
for Failure to Comply with Tenn. Code Ann. § 29-26-121

The undersigned counsel represents the following Tennessee clinics and individual health care providers:

1. Saint Thomas Outpatient Neurosurgical Center, LLC ("STOPNC")
2. Howell Allen Clinic, a Professional Corporation ("Howell Allen")
3. John W. Culclasure, MD ("Dr. Culclasure")
4. Debra V. Schamberg, RN ("Ms. Schamberg")
5. Specialty Surgery Center, Crossville, PLLC ("SSC")
6. Kenneth R. Lister, MD ("Dr. Lister")
7. Kenneth Lister, MD, PC ("Dr. Lister's Practice").

Collectively herein, these defendants shall be referred to as the "Tennessee Defendants."¹ These Tennessee clinics and individual health care providers are defendants, in various combinations, in scores of lawsuits in this MDL.

¹ A third Tennessee clinic-defendant, PCA Pain Care Center, Oak Ridge, has also been named in two suits filed on behalf of a single patient, *Seiber v. Ameridose, et al.*, No. 1:13-cv-11868-FDS and *Seiber v. Ameridose, et al.*, No. 1:14-cv-10273-FDS. The suits also name Donald E. Jones, MD, who is represented by counsel for the Tennessee Defendants. Case No. 1:13-cv-11868-FDS adds Dr. Jones by amendment with the Short Form Complaint, but it also incorporates the complaint filed in case No. 1:14-cv-10273-FDS by reference. Dr. Jones has not yet been served in either suit, but the Plaintiff's failure to comply with Tenn. Code Ann. § 29-26-121 is still noted in the attached Exhibit A.

On January 10, 2014, complying with this Court's order², these Defendants filed their Motion to Dismiss Plaintiffs' Complaints Against Tennessee Health Care Providers for Failure to Comply with Tenn. Code Ann. § 29-26-121.³ In the Motion, the Tennessee Defendants identified the dozens of complaints that failed to comply with the mandatory pre-suit notice requirements of Tenn. Code Ann. § 29-26-121.⁴ The Motion specified the case-specific deficiencies.⁵

The Tennessee Defendants submit this Memorandum of Law in Support of the Motion to Dismiss Plaintiffs' Complaints Against Tennessee Health Care Providers for Failure to Comply with Tenn. Code Ann. § 29-26-121.

Applying the law of the forum state to the deficiencies in pre-suit compliance explained here, the Tennessee Defendants request an order dismissing each complaint that failed to comply with the pre-suit requirements found at Tenn. Code Ann. § 29-26-121. The non-compliant cases are listed in Exhibit A to this Memorandum of Law, with the specific deficiencies identified.

² [Dkt. 723].

³ [Dkt. 770].

⁴ Tenn. Code Ann. § 29-26-121 establishes mandatory requirements that a Tennessee plaintiff must meet prior to filing a health care liability action, including written notice with precise content requirements, furnishing HIPAA-compliant releases for all potential defendants (allowing pre-suit access to complete medical records for investigation), and a minimum waiting period of sixty (60) days after the notice before filing suit. Non-compliance warrants dismissal.

⁵ [Dkt. 770].

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STATEMENT OF THE CASE

I. Introduction

These health care liability actions⁶ arise from the fungal meningitis outbreak caused by contaminated, preservative-free methylprednisolone acetate (“MPA”) manufactured by the New England Compounding Pharmacy, Inc. d/b/a the New England Compounding Center (“NECC”).

NECC sold contaminated MPA to health care providers, including STOPNC and SSC. Physicians caring for patients at those facilities, who had no knowledge or reason to know of the contamination, administered the MPA to patients during epidural steroid injection procedures. The Plaintiffs allege that the contaminated medication caused injury to patients across the country.

II. STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg

STOPNC is a licensed ambulatory surgery center located in Nashville, Tennessee, that ordered MPA from NECC. After NECC contaminated the medication, physicians at STOPNC unknowingly administered the contaminated MPA to patients.

Howell Allen, a neurosurgical group in Nashville, is a one-half owner of STOPNC. Howell Allen employees staffed STOPNC pursuant to a contract.

Dr. Culclasure, a board-certified anesthesiologist, is the Medical Director of STOPNC. He performed epidural steroid injection procedures at STOPNC using NECC MPA, including the injections at issue in many of the pending lawsuits. He also participated in the decision to purchase MPA from NECC.

⁶ In 2011, Tennessee’s Health Care Liability Act, Tenn. Code Ann. § 29-26-101, *et seq.* broadly redefined “medical malpractice” claims as “health care liability actions.”

Ms. Schamberg is the Facility Director of STOPNC. She also participated in the decision to purchase MPA from NECC.

STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg have been named, in various combinations, as defendants in suits filed by or on behalf of 117 patients related to the fungal meningitis outbreak. All suits against them allege injuries related to the injection of contaminated MPA at STOPNC. The suits against them assert, for the most part, the same causes of action.

III. SSC and Dr. Lister

SSC is a licensed ambulatory surgery center in Crossville, Tennessee, that, like STOPNC, received contaminated MPA from NECC.⁷

Dr. Lister, a board-certified anesthesiologist, is an owner of SSC. He performed epidural steroid injection procedures at SSC using contaminated NECC MPA. He also participated in the decision to purchase MPA from NECC for use at SSC.

SSC is a defendant in suits filed by or on behalf of 24 patients related to the fungal meningitis outbreak. Dr. Lister has been named as a defendant in ten of those suits.⁸ All suits against SSC and Dr. Lister allege injuries related to the injection of contaminated MPA at SSC. Like the suits against STOPNC, Howell Allen, Dr. Culclasure, and Ms. Schamberg, the suits against SSC and Dr. Lister assert, for the most part, the same causes of action.

⁷ SSC is separate and distinct from STOPNC. The relationship between the two facilities is limited to their representation by the same undersigned counsel. The legal issues explained in this submission apply equally to STOPNC, *et al.* and SSC, *et al.* Hence, undersigned counsel files a single brief.

⁸ Dr. Lister's practice – Kenneth Lister, MD, PC – is named as a defendant in five of these suits.

IV. Procedural posture

On December 23, 2013, the Court ordered Defendants to file a motion to dismiss cases in which the Plaintiff failed to satisfy pre-suit notice, certificate of good faith, and service requirements imposed by state law.⁹ The Tennessee Defendants did so at Docket 770. In the Motion, the Tennessee Defendants identified the non-compliant cases. The Tennessee Defendants now submit this Memorandum in Support of their previously-filed Motion to Dismiss.

Because the grounds supporting dismissal of the complaints for failure to comply with the pre-suit notice requirements are substantially the same for all Tennessee Defendants, these Tennessee Defendants address the Plaintiffs' failure to comply with the various aspects of § 29-26-121 in a "global" fashion, as the Court directed at the December 13, 2013, status conference.¹⁰

For the reasons discussed below, these Tennessee Defendants request an order from this Court dismissing the specific cases identified at Docket 770¹¹ as non-compliant with Tennessee's pre-suit notice requirements.

STANDARD OF REVIEW

Rule 12(b)(6) of the Federal Rules of Civil Procedure governs motions to dismiss for failure to state a claim upon which relief can be granted. Rule 12(b)(6) provides that

⁹ [Dkt. 723].

¹⁰ These Tennessee Defendants will file case-specific dispositive motions at a later date, as directed by the Court. Case-specific dispositive motions will include, but not be limited to, Plaintiffs' failure to file specific cases within the applicable statute of limitations.

¹¹ For the Court's convenience, the Tennessee Defendants have attached as Exhibit A the same chart that was attached as an exhibit to Docket 770. The chart identifies the individual violations of the notice requirements by specific case. The intent of this Memorandum of Law is to present the issues in "global" fashion such that the Court rule in "global" fashion on which deficiencies warrant dismissal of the complaint, and then the ruling(s) can be applied to individual, non-compliant cases.

a defense of “failure to state a claim upon which relief can be granted” may be raised by motion.¹²

A motion to dismiss is the proper method for challenging a plaintiff’s compliance with Tenn. Code Ann. § 29-26-121.¹³ Therefore, pursuant to Rule 12(b)(6), these Tennessee Defendants move to dismiss each of the Plaintiffs’ Complaints for failure to comply with Tenn. Code Ann. § 29-26-121, as specifically identified in Exhibit A and explained below, for failure to state a claim upon which relief can be granted.

LAW AND ARGUMENT

I. The Plaintiffs filed “health care liability actions” and are subject to the mandatory pre-suit requirements of the Tennessee Health Care Liability Act.

A. The Plaintiffs filed suits alleging injuries related to the provision of health care.

The Plaintiffs indisputably alleged injuries related to medical care.¹⁴

Therefore, the Plaintiffs have filed “health care liability actions,” as defined by Tenn. Code Ann. § 29-26-101(a)(1):

¹² FED. R. CIV. P. 12(b)(6).

¹³ See *Myers v. AMISUB (SFH), Inc.*, 382 S.W.3d 300, 307 (Tenn. 2012); *Childs v. UT Med. Group, Inc.*, 398 S.W.3d 163, 164-170 (Tenn. Ct. App. 2012); *Stevens v. Hickman Cmty. Health Care Servs., Inc.*, No. M2012-00582-SC-S09-CV, 2013 WL 6158000, at *1 (Tenn. Nov. 25, 2013) (slip copy); *Hawkins v. Martin*, No. W2011-02318-COA-R3-CV, 2012 WL 3007680, at *1-*2 (Tenn. Ct. App. July 24, 2012); *Thurmond v. Mid-Cumberland Infectious Disease Consultants, PLC*, No. M2012-02270-COA-R3CV, 2013 WL 1798960, at *3 (Tenn. Ct. App. Apr. 25, 2013) *cert. granted*, No. M2012-02270-COA-SC-R1-CV (Tenn. Aug. 13, 2013); *DePue v. Schroeder*, No. E2010-00504-COA-R9-CV, 2011 WL 538865, at *1-*9 (Tenn. Ct. App. Feb. 15, 2011) *cert denied*, No. E2010-00504-SC-R11-CV (Aug. 31, 2011); *Shockley v. Mental Health Coop., Inc.*, No. M2013-00494-COA-R3-CV, 2013 WL 5947764, at *4-*12 (Tenn. Ct. App. Sept. 25, 2013).

¹⁴ See, e.g., Master Compl., ¶ 17 (“Plaintiffs are individuals who suffered death, injury, or distress as a direct and proximate result of being administered one or more NECC Contaminated Drugs. . . by a defendant healthcare provider.”); *Pellicone, et al. v. Ameridose, et al.*, No. 1:13-cv-12916-FDS, Compl. ¶ 252 (“Saint Thomas Neurosurgical, acting through its physicians, nurses, managers, agents, and employees, was negligent in its care and treatment of Joseph Pellicone. Such care and treatment fell below the recognized standard of acceptable professional practice for pain management and drug procurement practices in this or similar communities and was a proximate cause of Joseph Pellicone’s injuries and damages. . . .”); *Graham v. Ameridose, et al.*, No. 1:13-cv-12581-FDS, Compl. ¶ 186 (“Specialty Surgery Center is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Danette Graham’s lumbar spine.”).

“Health care liability action” means any civil action, including claims against the state or a political subdivision thereof, alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, regardless of the theory of liability on which the action is based.¹⁵

By filing a “health care liability action,” the suits against these health care provider defendants are subject to the pre-suit requirements of the Tennessee Health Care Liability Act, including the pre-suit notice requirements:

Any such civil action or claim is subject to this part regardless of any other claims, causes of action, or theories of liability alleged in the complaint. . . .¹⁶

B. Tenn. Code Ann. § 29-26-121 requires that plaintiffs filing health care liability actions satisfy certain pre-suit notice requirements or face dismissal of the complaint.

As a prerequisite to filing a health care liability action, a plaintiff “shall give written notice of the potential claim to each health care provider that will be a named defendant at least sixty (60) days before the filing of a complaint. . . .”^{17 18}

The notice shall contain:

- (A) The full name and date of birth of the patient whose treatment is at issue;
- (B) The name and address of the claimant authorizing the notice and the relationship to the patient, if the notice is not sent by the patient;
- (C) The name and address of the attorney sending the notice, if applicable;
- (D) A list of the name and address of all providers being sent a notice; and

¹⁵ TENN. CODE ANN. § 29-26-101(a)(1) (emphasis added). “Health care services” is broadly defined to include care by any health care provider, including physicians, nurses, pharmacists, pharmacy technicians or interns, orderlies, nursing assistants, or any employee or representative of a health care provider, and even extends to “staffing, custodial or basic care, positioning, hydration and similar patient services.” TENN. CODE ANN. § 29-26-101(b).

¹⁶ TENN. CODE ANN. § 29-26-101(c).

¹⁷ TENN. CODE ANN. § 29-26-121(a)(1).

¹⁸ The notice requirements are “substantive law,” and, therefore, apply in federal court. *Shuler v. McGrew*, No. 12-2003-STA-dkv, 2012 WL 3260685, at *4 (W.D. Tenn. Aug. 8, 2012); *Williams v. United States*, 754 F. Supp. 2d 942, 951-52 (W.D. Tenn. 2010); *Conrad v. Washington Cnty.*, No 2:11-CV-106, 2012 WL 554462, at *2 (E.D. Tenn. Feb. 21, 2012).

- (E) A HIPAA compliant medical authorization permitting the provider receiving the notice to obtain complete medical records from each other provider being sent a notice.¹⁹

The purpose of the § 29-26-121 notice provision is to “reduce the number of frivolous lawsuits filed in Tennessee each year. . . by requiring early evaluation and streamlined disclosure of medical records.”²⁰ Tenn. Code Ann. § 29-26-121 allows defendants to quickly access the plaintiff’s medical records and assess the validity of the plaintiff’s claim.²¹ This process allows for quicker settlements and faster litigation, and it furthers the Tennessee legislature’s desire to drive down the cost of litigation.²²

In 2012, the Tennessee Supreme Court held that use of “shall” in § 29-26-121 dictates that courts must construe the requirements of § 29-26-121 as mandatory.²³ Defendants are not required to demonstrate prejudice in order to obtain dismissal of complaints that fail to comply with Tenn. Code Ann. § 29-26-121.²⁴ If a plaintiff fails to

¹⁹ TENN. CODE ANN. § 29-26-121(a)(2).

²⁰ *Jenkins v. Marvel*, 683 F. Supp. 2d 626, 639 (E.D. Tenn. 2010) (quoting TN Senate Republican Caucus Weekly Wrap, April 6, 2007 (available at <http://www.tnsenate.com/weekly/2007/04-06-07.htm>)).

²¹ *Hinkle v. Kindred Hosp.*, No. M2010-02499-COA-R3-CV, 2012 WL 3799215, at *6 (Tenn. Ct. App. Aug. 31, 2012); *Howell v. Claiborne & Hughes Health Ctr.*, No. M2009-01683-COA-R3-CV, 2010 WL 2359651, at *14 (Tenn. Ct. App. May 27, 2010).

²² *Hinkle*, No. M2010-02499-COA-R3-CV, 2012 WL 3799215, at *6; *Howell*, No. M2009-01683-COA-R3-CV, 2010 WL 2359651, at *14.

²³ *Myers v. AMISUB (SFH), Inc.*, 382 S.W.3d 300, 308-09 (Tenn. 2012); *See generally Stevens v. Hickman Cmty. Health Care Servs., Inc.*, No. M2012-00582-SC-S09-CV, 2013 WL 6158000, at *1 (Tenn. Nov. 25, 2013) (slip copy) (reading a subsection of § 29-26-121 to require substantial compliance).

²⁴ *Hawkins v. Martin*, No. W2011-02318-COA-R3-CV, 2012 WL 3007680, at *3-*4 (Tenn. Ct. App. 2012) (“[Plaintiff] asserts that, in this case, she substantially complied with the intent of the statute and Defendants were not prejudiced by her failure to include a HIPAA compliant authorization. . . . These arguments must fail for two reasons. First, we have held that a showing that the defendant was not prejudiced by non-compliance with the subsection 121(a) does not excuse such non-compliance under the express plain language of the statute. Second, we have held that substantial compliance with the ‘spirit’ of the statute is not sufficient to satisfy its mandatory language.”) (internal citations omitted); *see also Thurmond v. Mid-Cumberland Infectious Disease Consultants, PLC*, No. M2012-02270-COA-R3CV, 2013 WL 1798960, at *4 n.2 (Tenn. Ct. App. 2013) *cert. granted*, No. M2012-02270-COA-SC-R1-CV (Tenn. Aug. 13, 2013) (“We are cognizant of the harsh result reached in this case, where no one claims the notices were not sent or that any prejudice to the defendants existed. Yet, we are convinced the statute requires this result.”); *DePue v. Schroeder*, No. E2010-00504-COA-R9-CV, 2011 WL 538865, at *8 (Tenn. Ct. App. 2011) *cert denied*, No. E2010-00504-SC-R11-CV (Aug. 31, 2011) (“Upon review of the Trial Court’s Order, it is clear that the Trial Court applied an incorrect legal standard, as the Trial Court based its decision to grant the waiver on its finding that. . . ‘no prejudice resulted to defendants’ from the

comply with Tenn. Code Ann. § 29-26-121, regardless of whether it prejudiced the defendant, the plaintiff's complaint must be dismissed.²⁵

The pre-suit requirements cannot be ignored, and remedied later. A plaintiff cannot cure failure to comply with the mandatory pre-suit requirements through amendment of the complaint:

The statutes at issue [(Tenn. Code Ann. § 29-26-121 and -122)] do not authorize a claimant to cure deficiencies by filing an amended complaint, and as "[t]he essence of Tennessee Code Annotated section 29-26-121 is that a defendant be given notice of a medical malpractice claim before suit is filed," *Myers*, 382 S.W.3d at 309, the intent of the legislature is not realized by allowing the practice. Furthermore, we have previously held that timing is mandatory in these statutes.²⁶

In the actions at bar, the Plaintiffs, in various combinations, failed to comply with the following specific provisions of Tenn. Code Ann. § 29-26-121:

- Provide compliant notice at least 60 days before filing the complaint, in violation of Tenn. Code Ann. § 29-26-121(a)(1).
- Provide the full name and date of birth of the claimant (or the patient on whose behalf the claim is asserted), in violation of Tenn. Code Ann. § 29-26-121(a)(2)(A).
- Provide a list of the names and addresses of all providers being sent a notice, in violation of Tenn. Code Ann. § 29-26-121(a)(2)(D).
- Provide a HIPAA-compliant authorization permitting the provider receiving the notice to obtain complete medical records from each other provider being sent a notice, in violation of Tenn. Code Ann. § 29-26-121(a)(2)(E).

premature filing of the complaint. This is improper based on the plain language of the statute, which requires a showing of 'extraordinary cause', something obviously much greater than. . . lack of prejudice, as shown by the cases herein cited. The Trial Court's decision was an abuse of discretion and is reversed."); *Cude v. Herren*, No. W2010-01425-COA-R3-CV, 2011 WL 4436128, at *6 (Tenn. Ct. App. Sept. 26, 2011) ("[W]e reject Plaintiff's contention that her alleged substantial compliance with the statutory requirements and the alleged lack of prejudice to Defendant constitute extraordinary cause to support waiver of the statutory requirements.").

²⁵ See *id.*

²⁶ *Id.* Other Tennessee courts have consistently held that amendments do not cure pre-suit notice issues. See *Thurmond*, No. M2012-02270-COA-R3CV, 2013 WL 1798960, at *3; *Shockley*, No. M2013-00494-COA-R3-CV, 2013 WL 5947764, at *8-*9; *Garay*, No. 2:11-CV-128, 2013 WL 1249300, at *4-*5.

Non-compliance with the mandatory requirements of Tenn. Code Ann. § 29-26-121 is fatal, and mandates dismissal of the non-compliant complaints.^{27 28}

II. The Plaintiffs failed to comply with § 29-26-121 in multiple ways, warranting dismissal.

A. Various Plaintiffs did not give written notice of their potential claims at least 60 days before filing their Complaints.

To comply with Tenn. Code Ann. § 29-26-121(a)(1), the Plaintiffs must have provided the Tennessee Defendants with notice at least 60 days before filing their complaints.²⁹

In *DePue*, the plaintiff provided the defendant health care providers with notice but waited 53 (not the statutory 60) days before filing the complaint.³⁰ The Tennessee Court of Appeals reversed the trial court's denial of the defendants' motion to dismiss, holding the plaintiff's failure to comply with the plain language of Tenn. Code Ann. § 29-26-121(a)(1) mandated dismissal.³¹ The court's analysis was simple – the plaintiff did not wait 60 days – and that simple rationale has been consistently applied by courts, both state and federal, to dismiss complaints for failure to comply with Tenn. Code Ann. § 29-26-121(a)(1).³²

²⁷ The only exception is demonstration of "extraordinary cause," which no complaints have alleged.

²⁸ Illustrative cases dismissing the plaintiffs' complaints for failure to comply with Tenn. Code Ann. § 29-26-121 include: *Stevens*, No. M2012-00582-SC-S09-CV, 2013 WL 6158000, at *1; *Thurmond*, No. M2012-02270-COA-R3CV, 2013 WL 1798960, at *1 (Tenn. Ct. App. 2013); *DePue*, No. E2010-00504-COA-R9-CV, 2011 WL 538865, at *9; *Shockley*, No. M2013-00494-COA-R3-CV, 2013 WL 5947764, at *1.

²⁹ TENN. CODE ANN. § 29-26-121(a)(1).

³⁰ *DePue*, No. E2010-00504-COA-R9-CV, 2011 WL 538865, at *2.

³¹ *Id.* at *9.

³² *Id.*; *Moses v. Dirghangi*, No. W2011-02403-COA-R3-CV, 2013 WL 5519506, at *8 (Tenn.Ct.App. Oct. 3, 2013) (discussing the plaintiff's filing of her complaint 36 days after giving notice but dismissing the plaintiff's complaint for failure to comply with Tenn. Code Ann. § 29-26-122.); *Miller v. Monroe Cnty., Tennessee*, No. 3: 09-CV-85, 2010 WL 1427298, at *4 (E.D. Tenn. Apr. 7, 2010); *Garay*, No. 2:11-CV-128, 2013 WL 1249300, at *3-*5.

Numerous Plaintiffs, shown on the chart attached as Exhibit A to this Memorandum, failed to provide Tennessee Defendants with pre-suit notice at least 60 days before filing their complaints. These Plaintiffs failed to comply with the statutory notice period of Tenn. Code Ann. § 29-26-121(a)(1). Their complaints should be dismissed.

B. The Plaintiffs failed to include the name and address of Barry Cadden, NECC, and Ameridose in the Plaintiffs' notice letters to Tennessee Defendants.

1. Tenn. Code Ann. § 29-26-121(a)(1) requires that a plaintiff provide a potential defendant with the name and address of any health care provider being sent a notice of intent.

Tenn. Code Ann. § 29-26-121(a)(1) mandates that plaintiffs give written notice of their potential claims *to each health care provider who will be a named defendant*.³³ Tenn. Code Ann. § 29-26-121(a)(2)(D) adds the requirement that plaintiffs give each health care provider that will be a named defendant *a list of the names and addresses for all other health care providers being sent a notice*.³⁴

This requirement is not simply technical. It permits the health care providers receiving notice to promptly obtain records from the other health care providers receiving notice³⁵ and furthers the Tennessee legislature's desire to drive down the cost of litigation by allowing an informed pre-suit investigation of the claim³⁶.

³³ TENN. CODE ANN. § 29-26-121.

³⁴ *Id.*

³⁵ See TENN. CODE ANN. § 29-26-121(d)(1).

³⁶ *Hinkle v. Kindred Hosp.*, No. M2010-02499-COA-R3-CV, 2012 WL 3799215, at *6 (Tenn. Ct. App. Aug. 31, 2012); *Howell v. Claiborne and Hughes Health Ctr.*, No. M2009-01683-COA-R3-CV, 2010 WL 2359651 at *14 (Tenn. Ct. App. May 27, 2010).

2. Barry Cadden, NECC, and Ameridose are “health care providers” as defined by Tenn. Code Ann. § 29-26-101(a)(2)(A).

In the same statutory section as Tenn. Code Ann. § 29-26-121, the term “health care provider” is defined as:

A health care practitioner licensed, authorized, certified, registered, or regulated under any chapter of title 63 or title 68, including, but not limited to, medical resident physicians, interns, and fellows participating in a training program of one of the accredited medical schools or of one of such medical school's affiliated teaching hospitals in Tennessee.³⁷

Pharmacists, pharmacies, and manufacturer/wholesaler/distributors are licensed, authorized, certified, registered, and/or regulated by the Tennessee Board of Pharmacy under the authority granted to it by the Tennessee legislature in Title 63, Chapter 10.³⁸ Tenn. Code Ann. § 29-26-101(b) specifically lists services provided by pharmacists and employees of pharmacists (including, specifically, pharmacy interns or pharmacy technicians) in the definition of “health care services.”³⁹

Barry Cadden was a licensed Tennessee pharmacist, holder of license number 22971, until he voluntarily surrendered his Tennessee pharmacy license on October 23, 2012.⁴⁰ NECC was a licensed Tennessee pharmacy, license number 00004144, until the voluntary surrender of its Tennessee pharmacy license on October 15, 2012.⁴¹ Ameridose remains a licensed Tennessee pharmacy, license number 00004760.⁴² Ameridose was also a licensed Tennessee manufacturer / wholesaler / distributor,

³⁷ TENN. CODE ANN. § 29-26-101(a)(2)(A) (emphasis added).

³⁸ TENN. CODE ANN. § 63-10-101, *et seq.*

³⁹ TENN. CODE ANN. § 29-26-121(b) (“which includes care by physicians, nurses, licensed practical nurses, pharmacists, pharmacy interns or pharmacy technicians under the supervision of a pharmacist...”).

⁴⁰ <http://health.state.tn.us/licensure/Results.aspx> (Barry Cadden's Tennessee License Number) (last accessed February 2, 2014).

⁴¹ http://health.state.tn.us/HCF/Facilities_Listings/CurrentResults.asp (last accessed February 2, 2014).

⁴² http://health.state.tn.us/HCF/Facilities_Listings/CurrentResults.asp (last accessed February 2, 2014).

license numbers 00002640 and 00002991, until the expiration of its licenses on March 31, 2013, and April 30, 2013.⁴³ ⁴⁴

Barry Cadden, NECC, and Ameridose were health care providers as defined by the pre-suit notice statutory section.

3. The Plaintiffs did not provide Tennessee Defendants with notice that Barry Cadden, NECC, and Ameridose would be named defendants.

The plain language of Tenn. Code Ann. § 29-26-121(a)(2)(D) required the Plaintiffs to provide notice to these Tennessee Defendants of *all* health care providers who would be named as defendants. No exception to Tenn. Code Ann. § 29-26-121 excuses lack of pre-suit notice of the claims against Barry Cadden, NECC, and Ameridose named as defendants in scores of cases.

The Plaintiffs' failure to identify other health care providers who must also receive pre-suit notice violated the clear language of Tenn. Code Ann. § 29-26-121(a)(2)(D). Such non-compliance with the notice requirements mandates dismissal.⁴⁵

4. By failing to provide a HIPAA release that permitted these Tennessee Defendants to obtain records from Barry Cadden, NECC, or Ameridose, Plaintiffs' HIPAA releases do not enable Tennessee Defendants to obtain the Plaintiffs' *complete* medical records, as required by the statute.

Tenn. Code Ann. § 29-26-121(a)(2)(E), requires the plaintiffs to provide Tennessee Defendants with (1) a HIPAA-compliant medical authorization (2) permitting Tennessee Defendants to obtain the *complete* medical records (3) from all other providers who will become defendants in a later-filed action.

⁴³ *Id.*

⁴⁴ During the relevant time period, Ameridose also possessed pharmacy facility license number 00004761, which expired on March 31, 2013.

⁴⁵ Again, notably, a showing of prejudice is not necessary.

None of the Plaintiffs provided Tennessee Defendants with HIPAA releases permitting Tennessee Defendants to obtain the patients' medical records from health care providers Barry Cadden, NECC, or Ameridose, as required by the statute. By failing to do so, the Plaintiffs failed to provide HIPAA releases permitting the release of the patients' *complete* medical records, in violation of Tenn. Code Ann. § 29-26-121(a)(2)(E).

This violation is likewise fatal to the Plaintiffs' complaints.

C. Various Plaintiffs failed to provide the patients' full names in violation of Tenn. Code Ann. § 29-26-121(a)(2)(A).

Tenn. Code Ann. § 29-26-121(a)(2)(A) requires that a plaintiff serving pre-suit notice shall provide the full name and date of birth of the patient whose treatment is at issue.⁴⁶

Tennessee courts presume *every* word in a statute has meaning and purpose, and that the statute should be given *full* effect.⁴⁷ When a statute is clear, Tennessee courts apply the plain meaning without complicating the task.⁴⁸

The Plaintiffs identified in Exhibit A failed to provide the patient's full name in their notice letters. These Plaintiffs' Complaints should be dismissed.⁴⁹

⁴⁶ TENN. CODE ANN. § 29-26-121(a)(2)(A).

⁴⁷ *In re C.K.G.*, 173 S.W.3d 714, 722 (Tenn. 2005).

⁴⁸ *Eastman Chem. Co. v. Johnson*, 151 S.W.3d 503, 507 (Tenn. 2004).

⁴⁹ This admittedly technical violation has not been tested as a means for dismissal in Tennessee's appellate courts. While the deficiency is technical, it affects a potential defendant's ability to investigate a case by complicating obtaining records in some instances. The presumption is that the words of a statute have meaning, *Morgan Keegan & Co., Inc. v. Smythe*, 401 S.W.3d 595, 602 (Tenn. 2013), and prejudice is not a necessary showing for dismissal, *Hawkins*, No. W2011-02318-COA-R3-CV, 2012 WL 3007680, at *3-*4.

D. Various Plaintiffs failed to comply with Tenn. Code Ann. § 29-26-121(a)(2)(E) by failing to provide a HIPAA-compliant medical authorization.

Not less than sixty (60) days before filing suit, Tenn. Code Ann. § 29-26-121(a)(2)(E) required the Plaintiffs to provide Tennessee Defendants with a HIPAA-compliant medical authorization allowing records requests to all potential defendants. The potential defendants then are able to use the HIPAA-compliant authorization to obtain the records as part of the pre-suit investigation.

The Plaintiffs identified in Exhibit A failed to provide Tennessee Defendants with HIPAA-compliant medical authorizations permitting Tennessee Defendants to obtain the patients' complete medical records from all other Defendant providers. Notably, some of these Plaintiffs did not provide any notice of intent⁵⁰ or any HIPAA releases.⁵¹ Others simply did not comply with the requirements of HIPAA in providing the release.

The deficiencies in the various Plaintiffs' HIPAA releases are identified in Exhibit A. In Exhibit B, the Defendants categorize examples of the deficient HIPAA authorizations for the Court. The common and repeated deficiencies in the HIPAA releases include:

- Providing HIPAA releases that failed to meet the mandatory requirements of HIPAA, codified at 45 C.F.R. §164.508(c) and discussed more fully below,
- Providing HIPAA releases that do not permit Tennessee Defendants to obtain the patient's complete medical records, including:
 - Providing HIPAA releases that included a timeframe which limited Tennessee Defendants to receiving the patient's medical records only for

⁵⁰ See, e.g., *Keyes v. Ameridose, et al.*, No. 1:13-cv-12998, Compl.

⁵¹ See, e.g., *Carter, et al. v. Ameridose, et al.*, No. 1:13-cv-12187-FDS, Compl. Ex. A; attached hereto, in relevant part, in Exhibit B. See also the affidavit of counsel, attached as Exhibit C to this Memorandum, which attests that the release was not included with the notice of intent.

treatment from June 1, 2012, to present or another similar and arbitrary time period,⁵² and

- Providing HIPAA releases that only authorized disclosure of records to the Plaintiffs' law firm.^{53 54}

Stevens is the controlling, contemporary Tennessee Supreme Court decision addressing a plaintiff's failure to provide the defendants with a HIPAA-compliant medical authorization as a part of the pre-suit notice process required by Tenn. Code Ann. § 29-26-121.⁵⁵ *Stevens* should guide this Court in responding to the instant Plaintiffs' deficient HIPAA authorizations.

1. *Stevens v. Hickman Cmty. Health Care Servs., Inc.*

In *Stevens*, the plaintiff provided the defendants with a pre-suit authorization to obtain records, but the release was deficient in numerous ways, including:

- The HIPAA release did not allow the health care provider to obtain the patient's medical records from the other notice recipients;
- The release lacked a description of the medical information to be disclosed in violation of the mandatory requirement of 45 C.F.R. §164.508(c)(1)(i);
- The release failed to state the individuals or organizations authorized to disclose the patient's medical records in violation of the mandatory requirement of 45 C.F.R. §164.508(c)(1)(ii); and
- The release failed to specify the purpose of the disclosure in violation of the mandatory requirement of 45 C.F.R. §164.508(c)(1)(iv).⁵⁶

⁵² See, e.g., *Brock, et al. v. Ameridose, et al.*, No. 1:13-cv-12731-FDS, Compl. Ex. A; attached hereto, in relevant part, in Exhibit B.

⁵³ See, e.g., *Patel, et al. v. Ameridose, et al.*, No. 3:14-cv-12731-FDS, Compl. Ex. 3; attached hereto in Exhibit B.

⁵⁴ This obviously defeats the purpose of allowing the defendant to conduct a meaningful pre-suit evaluation of the case and was explicitly recognized as a ground for dismissal in *Stevens v. Hickman Cmty. Health Care Servs., Inc.*, No. M2012-00582-SC-S09-CV, 2013 WL 6158000, at *4 (Tenn. Nov. 25, 2013) (slip copy) ("by permitting disclosure only to Plaintiff's counsel, Plaintiff's medical authorization failed to satisfy the express requirement of Tenn. Code Ann. § 29-26-121(a)(2)(E). . .").

⁵⁵ *Stevens v. Hickman Cmty. Health Care Servs., Inc.*, No. M2012-00582-SC-S09-CV, 2013 WL 6158000, at *1 (Tenn. Nov. 25, 2013) (slip copy).

⁵⁶ *Id.* at *4.

The Tennessee Supreme Court found that the plaintiff's failures to comply with the mandatory, technical requirements of HIPAA were "numerous and significant," and:

Due to Plaintiff's material non-compliance [with the mandatory requirements of HIPAA], Defendants were not authorized to receive any of the Plaintiff's records. As a result of multiple errors, Plaintiff failed to substantially comply with the requirements of Tenn. Code Ann. § 29-26-121(a)(2)(E).⁵⁷

The Tennessee Supreme Court dismissed the plaintiff's complaint for failing to provide a "substantially compliant" HIPAA authorization with the pre-suit notice documents.⁵⁸

2. Multiple Plaintiffs' HIPAA releases do not comply with 45 C.F.R. § 164.508(c).

Tenn. Code Ann. § 29-26-121(a)(2)(E) and the Tennessee Supreme Court's holding in *Stevens* together lead to one (1) conclusion – Plaintiffs failing to provide HIPAA-compliant medical authorizations will have their Complaint dismissed⁵⁹

Failure to comply with HIPAA when providing a purportedly "HIPAA compliant" medical authorization constitutes a failure to follow the notice requirements of -121, as applied in *Stevens*. As described in the chart in Exhibit A and as demonstrated in the exemplar non-compliant HIPAA authorizations attached as Exhibit B, the Plaintiffs' HIPAA releases are invalid for the following reasons (some cases fitting more than one category):

1. The Plaintiffs failed to provide a description of the information to be used or disclosed in the release.⁶⁰
2. The Plaintiffs failed to state in the release the individuals or organizations authorized to disclose the patient's medical records.⁶¹

⁵⁷ *Id.* at *5.

⁵⁸ *Id.* at *9.

⁵⁹ *Id.*; TENN. CODE ANN. § 29-26-121(a)(2)(E); 45 C.F.R. §164.508(c).

⁶⁰ 45 C.F.R. §164.508(c)(1)(i); *see, e.g., Judd, et al. v. Ameridose, et al.*, No. 1:13-cv-13120-FDS, Compl. Ex. F; attached hereto, in relevant part, in Exhibit B.

3. The Plaintiffs failed to state in the release the individuals or organizations authorized to receive the patient's medical records.⁶²
4. The Plaintiffs failed to state in the release the purpose of the disclosure.⁶³
5. The Plaintiffs failed to include in the release an expiration date or termination event.⁶⁴
6. The Plaintiffs failed to include the signature and date of the patient or patient's representative's authorization in the release.⁶⁵
7. The Plaintiffs failed to include in the release a statement regarding the ability or inability of a health care provider to condition treatment contingent on the patient signing the authorization.⁶⁶
8. The Plaintiffs failed to include in the release a statement regarding the potential for information disclosed pursuant to the authorization to be subject to re-disclosure and no longer protected by HIPAA.⁶⁷

⁶¹ 45 C.F.R. §164.508(c)(1)(ii); see, e.g., *Sawyers, et al. v. Ameridose, et al.*, No. 1:13-cv-12491-FDS, Compl. Ex. 1; attached hereto, in relevant part, in Exhibit B.

⁶² 45 C.F.R. §164.508(c)(1)(iii); see, e.g., *Besaw, et al. v. Ameridose, et al.*, No. 1:13-cv-12604-FDS, Compl. Ex. 7A; attached hereto in Exhibit B.

⁶³ 45 C.F.R. §164.508(c)(1)(iv); see, e.g., *Siler, et al. v. Ameridose, et al.*, No. 1:13-cv-12489-FDS; *Tyree, et al. v. Ameridose, et al.*, No. 1:13-cv-12479. However, Plaintiffs in *Siler* and *Tyree* did not attach their HIPAA releases to their Complaints in violation of Tenn. Code Ann. § 29-26-121(b). Failure to comply with Tenn. Code Ann. § 29-26-121(b) is an independent ground for dismissal. *Vaughn v. Mountain States Health Alliance*, No. E2012-01042-COA-R3-CV, 2013 WL 817032, at *6 (Tenn. Ct. App. March 5, 2013); *Miller v. Uchendu*, No. 2:13-cv-02149-JPM-dkv, 2013 WL 4097340, at *5 (W.D. Tenn. Aug. 13, 2013). Therefore, the Plaintiffs' Complaints in *Siler* and *Tyree* should be dismissed for failure to comply with Tenn. Code Ann. § 29-26-121(a)(2)(E) and (b), amongst the other grounds identified in Exhibit A. For the Court's convenience, these Tennessee Defendants have attached as examples in Exhibit B the HIPAA releases sent to these Tennessee Defendants in *Siler* and *Tyree*.

⁶⁴ 45 C.F.R. §164.508(c)(1)(v); see, e.g., *Siler, et al. v. Ameridose, et al.*, No. 1:13-cv-12489-FDS; *Tyree, et al. v. Ameridose, et al.*, No. 1:13-cv-12479. However, as discussed previously, Plaintiffs in *Siler* and *Tyree* did not attach their HIPAA releases to their Complaints in violation of Tenn. Code Ann. § 29-26-121(b). For the Court's convenience, these Tennessee Defendants have attached in Exhibit B the HIPAA releases sent to these Tennessee Defendants.

⁶⁵ 45 C.F.R. §164.508(c)(1)(vi); see, e.g., *Ferguson, et al. v. Ameridose, et al.*, No. 1:13-cv-12571-FDS, Compl. Ex. 7A; attached hereto, in relevant part, in Exhibit B. See also the affidavit of counsel, attached as Exhibit C to this Memorandum of Law, which attests that the original releases did not include dates.

⁶⁶ 45 C.F.R. §164.508(c)(2)(ii); see, e.g., *Higdon, et al. v. Ameridose, et al.*, No. 1:13-cv-12718, Compl. Ex. F; attached hereto in Exhibit B; see also *Alexander, et al. v. Ameridose, et al.*, No. 1:13-cv-12428-FDS; *Lapiska v. Ameridose, et al.*, No. 1:13-cv-12914; *Nealon v. Ameridose, et al.*, No. 1:13-cv-12491; *Peay v. Ameridose, et al.*, No. 1:13-cv-12843; *Schulz, et al. v. Ameridose, et al.*, No. 1:13-cv-12311; However, Plaintiffs in *Alexander, Lapiska, Nealon, Peay, and Schulz* did not attach their HIPAA releases to their Complaints in violation of Tenn. Code Ann. § 29-26-121(b). Failure to comply with Tenn. Code Ann. § 29-26-121(b) is an independent ground for dismissal. *Vaughn*, E2012-01042-COA-R3-CV, 2013 WL 817032, at *6; *Miller*, No. 2:13-cv-02149-JPM-dkv, 2013 WL 4097340, at *5. Therefore, the Plaintiffs' Complaints in *Alexander, Lapiska, Nealon, Peay, and Schulz* should be dismissed for failure to comply with Tenn. Code Ann. § 29-26-121(a)(2)(E) and (b), amongst the other grounds identified in Exhibit A.

Multiple Plaintiffs failed to provide Tennessee Defendants with HIPAA-compliant releases in violation of Tenn. Code Ann. § 29-26-121(a)(2)(E), with the non-compliant cases and specific violations delineated in Exhibit A. Therefore, these Plaintiffs' Complaints should be dismissed for failing to comply with the statutory requirement to deliver a HIPAA-compliant authorization not less than sixty (60) days before suit is filed.⁶⁸

Conclusion

Each of the Tennessee Plaintiffs initiated health care liability actions asserting injuries related to the provision of health care services. As a prerequisite to filing their health care liability actions, the Plaintiffs were required to give Tennessee Defendants pre-suit notice in compliance with Tenn. Code Ann. § 29-26-121.

The Plaintiffs, for the reasons stated above, did not comply with Tenn. Code Ann. § 29-26-121. The Plaintiffs have not pled an extraordinary cause for their non-compliance, and they cannot cure their deficiencies through amendment. It is irrelevant whether the Defendants were prejudiced by the Plaintiffs' non-compliance.

The Tennessee Defendants request the Court enter an order finding that the above-described deficiencies in the notice procedure warrant dismissal of the non-compliant Plaintiffs' complaints for failure to comply with Tenn. Code Ann. § 29-26-121.

⁶⁷ 45 C.F.R. §164.508(c)(2)(iii); see, e.g., *Lapiska v. Ameridose, et al.*, No. 1:13-cv-12914; *Peay v. Ameridose, et al.*, No. 1:13-cv-12843. However, as discussed previously, Plaintiffs in *Lapiska* and *Peay* did not attach their HIPAA releases to their Complaints in violation of Tenn. Code Ann. § 29-26-121(b). For the Court's convenience, these Tennessee Defendants have attached these releases as part of Exhibit B.

⁶⁸ The moving Defendants need not show prejudice to justify dismissal of the complaint for non-compliance with § 29-26-121. However, the requirement that a plaintiff provide a HIPAA-compliant authorization is not hollow. Attached as Exhibit C to this Memorandum of Law is an affidavit from counsel attesting to the various cases in which these Defendants were specifically unable to obtain records pre-suit because the authorization provided was not compliant with HIPAA.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/Chris J. Tardio

C.J. Gideon, Jr. (admitted *pro hac vice*)

Chris J. Tardio (admitted *pro hac vice*)

Matthew H. Cline

John-Mark Zini

315 Deaderick Street, Suite 1100

Nashville, TN 37238

Ph: (615) 254-0400

Fax: (515) 254-0459

chris@gideoncooper.com

***Attorneys for STOPNC, Howell Allen,
John W. Culclasure, MD, Debra V.
Schamberg, RN, SSC, Kenneth R.
Lister, MD, and Kenneth Lister, MD,
PC***

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 7th day of February, 2014.

/s/ Chris Tardio

Chris Tardio